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Dear Prescriber:

On January 2, 2008, MassHealth will be launching a new initiative involving Subutex (buprenorphine) and Suboxone (buprenorphine/naloxone). Prior authorization (PA) may be required depending on dose and duration of treatment. You have been identified as a registered prescriber for these medications, and MassHealth would like to work closely with you to ensure appropriate continuity of care for your patients currently taking these medications for the treatment of opioid dependence.

Subutex. Your patients who have prescriptions for Subutex dated before January 2, 2008, will be allowed to continue to fill the existing refills on that prescription. Any new prescription written after January 2, 2008, will require prior authorization**.**

Suboxone. Your patients with prescriptions written for Suboxone before January 2, 2008, will also be able to continue receiving the authorized refills without requiring prior authorization. After January 2, 2008, prior-authorization status will depend on daily dose and duration of therapy.

New Prior Authorization Requirement. The following guidelines are effective January 2, 2008.

Daily dose of buprenorphine (in Suboxone)	**Prior authorization will be required for:**
>32 mg/day	all new scripts for doses over 32 mg/daily will require a prior authorization
>24 and ≤32 mg/day	new prescriptions written after 90 days of therapy to continue therapy within this dose range
>16 and ≤ 24 mg/day	new prescriptions written after 180 days of therapy to continue therapy within this dose range
≤ 16 mg/day	new prescriptions written after 365 days of therapy

The above time frames will start with the beginning of the initiative on January 2, 2008. Please consider these time frames when writing prescriptions for your patients so that therapy is not disrupted.

The recommended target dose is 16 mg/day. Doses up to 24 mg/day may be required to hold the patient in treatment and suppress opioid withdrawal effects. There is little evidence in the published literature to support doses over 32 mg/day. The start of this initiative on January 2, 2008, will not disrupt your patients' authorized refills. However, new prescriptions that exceed the dose and timelines outlined above will require the prescriber to provide medical necessity through the PA process to justify why the member requires doses higher than the recommended targets.

Continuation of Therapy. All new requests for prior authorizations to continue Suboxone or Subutex therapy must explain why your patient is not in the process of dose reduction or discontinuation of the therapy.

Dose consolidation. Both Suboxone and Subutex are available in 2-mg and 8-mg sublingual tablets. Consider a simplified dosing regimen using the smallest number of tablets to reach a specific daily dose.

To assist you in this transition period, MassHealth has compiled a list of "Questions and Answers" about this initiative, as well as a dedicated PA form used for Suboxone and Subutex requests.

We appreciate your support and efforts in assisting MassHealth in this new initiative.

Sincerely,

Paul L. Jeffrey, PharmD
Pharmacy Director
MassHealth

[Enclosures: 2]

Suboxone/Subutex Initiative

Questions & Answers

Q1: Which prior authorization (PA) form should I use to request Suboxone or Subutex for my patient?

A1: There is a dedicated Suboxone/Subutex PA form, which is enclosed for your convenience. You may also use the general "Drug Prior Authorization Request" form to initiate the request.

Q2: My patient is currently taking ≤24 mg/day of Suboxone, which is within the recommended dosing of the medication. Will I need to submit a PA request for my patient?

A2: Your patient will be able to obtain all remaining refills on his or her prescription. The member will be able to fill any new prescriptions at ≤24 mg/day for 6 months without prior authorization. If the dose is decreased to less than 16 mg/daily, prior authorization would not be required for 12 months. Please consider the time frames outlined above when writing prescriptions so that patients' therapy is not disrupted.

Q3: My patient is currently taking >24 mg/day but ≤32 mg/day of Suboxone and there are studies showing clinical efficacy at this dose for treating opioid dependence. What additional information do I need to submit with the PA request?

A3: The manufacturer's package insert recommends a buprenorphine target dose of 16 mg/day. The buprenorphine target dose will vary but is typically between 12 and 16 mg/day with a daily dose ranging from 4 mg to 24 mg according to clinical studies[2]. You will need to document the rationale and submit medical records supporting the medical necessity in prescribing >24 mg/day of Suboxone or Subutex. Note: there is currently no clinical evidence to support daily dosing of >32 mg Suboxone or Subutex. All prior-authorization requests will be reviewed on a case-by-case basis.

Q4: My patient has been on Suboxone or Subutex therapy but now requires prior authorization. What can be done to prevent disruption of therapy while the prior-authorization request is reviewed?

A4: As with any medication, the pharmacy can provide the member with a 3-day emergency supply while waiting for the prior authorization to be reviewed.

Q5: How long is a Suboxone or Subutex request typically approved for?

A5: Requests are reviewed on a case-by-case basis. Generally, Suboxone or Subutex prior- authorization requests may be approved for 1 to 6 months at a time.

1. Center for Substance Abuse Treatment. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); DHHS Publication No. (SMA) 04-3939. 2004.
2. Suboxone (buprenorphine HCl and naloxone HCl dehydrate sublingual tablets), Subutex (buprenorphine sublingual tablets) [package insert]. Richmond, VA: Reckitt Benckiser Pharmaceuticals, Inc.; June 2005.
3. Alford DP, Compton P, Samet JH. Acute pain management for patients receiving maintenance methadone or buprenorphine therapy. Ann Intern Med. 2006;144(2):127-134.
4. Mattick RP, Kimber J, Breen C, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. [Systematic Review] Cochrane Drugs and Alcohol Group Cochrane Database of Systematic Reviews. 1, 2007.
5. Robinson SE. Buprenorphine-containing treatments: place in the management of opioid addiction. CNS Drugs. 2006;20(9):697-712.